IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Art Unit: 1614
Olie KORSGREN et al	Examiner: Donna A. Jagoe
I.A. Filing Date: 02/04/2000 371(c) Date: November 7, 2001	Washington, D.C.
	Confirmation No. 9165
U.S. Appln. No.: 09/890,936	
For: NOVEL USE WITHIN TRANSPLANTATION SURGERY	ATTY.'S DOCKET: KORSGREN=1

DECLARATION OF JAMES SHAPIRO, M.D., PH.D., FRCSC

I, James Shapiro, hereby solemnly declare as follows:

I am Director, Clinical Islet Transplant Program, University of Alberta, Canada. Attached is an abbreviated form of my *Curriculum Vitae.*, which is made a part of this declaration. I have a Ph.D. degree and MD degree and have published more than 200 scientific papers including the paper from 2000 known as the Edmonton Protocol. Between 2005 and 2007, I was the President of the International Pancreas and Islet Transplantation Association.

I know Rolf Larsson, one of the inventors of the above-identified application, but I have no professional relationship with Professor Larsson or with the assignee of the above-identified U.S. patent application, Corline Systems AB. I have been asked to submit a statement with regard to the meaning of certain terms in the above-identified U.S.

patent application, as an independent expert in the field of transplantation of islets of Langerhans.

I have carefully reviewed the above-identified U.S.S patent application 09/890,936, as well as the first and second Declarations filed in the above-identified application. I have also reviewed the latest Office Action explaining the views of the Examiner.

My understanding of the Examiner's commentary is that the examiner believes that there is a difference between the terminology "individually isolated islets" and "isolated islets". But the examiner's understanding is incorrect because the two phrases, "isolated islets" and "individually isolated islets", are entirely equivalent, and refer to islets extracted from whole pancreas through mechanical and enzymatic techniques, followed by density purification to enrich the proportion of islets over the remnant contaminating exocrine cellular components.

I understand from the patent application specification of 09/890,936 that the "isolated islets" are "individually isolated islets", without any question.

It is also my professional opinion that workers in the field of islets research and related fields, including scientists involved in this area, would also understand that

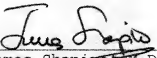
the term "isolated islets" means that such "isolated islets" are "individually isolated islets."

The terms "isolated islets" and "individually isolated islets" are quite distinct from another term, islet encapsulation, the latter term of which refers specifically to immunological isolation of islets from attacking immune damaging cells.

I understand from reading the specification of the above-identified application 09/890,936 that the individually isolated islets are treated with a clotting inhibiting agent, e.g. heparin or soluble Corline heparin conjugate, which is adsorbed onto the surface of the individual isolated islets. This adsorption of clotting inhibiting agent onto the individual isolated islets is quite different from islet encapsulation, the latter of which refers specifically to immunological isolation of islets from attacking immune damaging cells.

There is no confusion between these terms throughout the islet research field, and all scientist involved in this area would certainly comprehend the distinction between immune isolation (encapsulation) as opposed to isolated or individually isolated islets, namely islets which have been extracted from their exocrine matrix.

I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

By 
James Shapiro, M.D., Ph.D., FRCSC

Date: 8th December 2007

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Who is in the CIT Consortium?

James Shapiro, M.D., Ph.D., FRCSC

Born in Leeds, England, Dr James Shapiro obtained his Medical Degree at the University of Newcastle-upon-Tyne and trained in Surgery at the University of Bristol. In 1993, He came to the University of Alberta in Canada to train in liver transplantation and hepatobiliary surgery, continuing research studies in experimental islet transplantation begun as a medical student. He earned a Ph.D. studying new drug combinations for possible testing in islet transplantation. He then further trained in liver surgery in Vancouver, in living donor liver transplant surgery in Japan, and in whole pancreas transplant surgery at the University of Maryland. In 1998, he returned to the University of Alberta as a multi-organ transplant surgeon.

Dr. Shapiro was asked to lead the Clinical Islet Transplant Program team in Edmonton; Together with Drs. Lakey, Ryan, Rajotte, Kneteman and Korbutt, he developed and tested a new protocol that used a steroid-free anti-rejection regimen coupled with sufficient numbers of transplanted islets. This research has since become known as the "Edmonton Protocol." In 1999, Dr. Shapiro initiated the pancreas transplant program at the University of Alberta, and in the same year performed the first emergency living-related donor liver transplant in Canada.

Dr. Shapiro is Principal Investigator of the international multi-center trial of islet transplantation testing the Edmonton Protocol at 9 international sites, sponsored by the Immune Tolerance Network. He is also Principal Investigator and Director of the Juvenile Diabetes Research Foundation (JDRF) Clinical Center for Islet Transplantation created in 2001 at the University of Alberta. In 2002, Dr. Shapiro was awarded the Canadian Institutes of Health Research/Wyeth Clinical Research Chair in Transplantation at the University of Alberta.

In 2005,Dr. Shapiro received a Meritorious Service Medal from the Governor General of Canada for his work towards the development of a new treatment for Diabetes. He was also named one of the "Physicians of the Century", by the College of Physicians and Surgeons of Alberta and the Alberta Medical Association. In 2006, he was named one of Nature Biotechnology's most remarkable and influential personalities from the past 10 years, in Biopharmaceuticals.

Dr. Shapiro maintains an active immunology/transplant research laboratory focused on aspects of tolerance induction relating to islet transplantation with emphasis on costimulatory blockade and chimerism, with translational potential to clinical islet recipients. In early 2004, Dr. Shapiro was awarded an Alberta Heritage Foundation for Medical Research Scholarship to support his on-going tolerance research.

Clinical Islet Transplant Program, University of Alberta

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